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SETH A. GOLDBERG
DIRECT DIAL: +1 215 979 1175
PERSONAL FAX: +1 215 689 2198
E-MAIL: SAGoldberg@duanemorris.com

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November 15, 2021

VIA ECF

The Honorable Thomas Vanaskie
Special Discovery Master
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Case No. 1:19-md-02875-RBK-KW

Dear Judge Vanaskie:

We write on behalf of the ZHP Parties to address the proposed order that Plaintiffs filed with their opposition (the "Opposition," ECF No. 1736) to the ZHP Parties' motion to seal, and respectfully request that Your Honor accept this letter in lieu of a formal reply brief.

In response to the ZHP Parties' motion to seal ten exhibits (the "Motion," ECF No. 1629), Plaintiffs' proposed order demands that the ZHP Parties be ordered to re-review and de-designate confidentiality designations in their entire production—

some ***three million*** pages. This overreaching by Plaintiffs would jettison the document-by-document approach to determining confidentiality required by the Third Circuit Court of Appeals, the Court's previous rulings, and the Court's Confidentiality and Protective Order itself. *See, e.g., In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.,* 924 F.3d 662, 673 (3d. Cir. 2019) ("the District Court must 'conduct[] a document-by-document review' of … the challenged documents"); *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, MDL No. 2875, Order dated May 24, 2021 at 9 n.3 (ECF No. 1269) ("categorization" of challenged documents "does not obviate a document-by-document review"); and ECF No. 1661 at ¶ 20 (parties must object "with particularity").

The proposed order is also procedurally improper as the Motion concerns only ten documents whose confidentiality designations Plaintiffs have challenged. Without submitting a cross-motion or otherwise moving for the drastic relief they are now improperly requesting, Plaintiffs are suggesting the entry of an order that would, without justification, require the ZHP Parties to incur significant time and expense in a wholesale review of their entire documentary production. Plaintiffs' proposed order also flouts what even Plaintiffs acknowledge was this Court's "cautioning" of Plaintiffs that they should be more specific in their objections to the Defendants' confidentiality designations. *See* Opp. at 2 ("The Court recently

cautioned Plaintiffs regarding the confidentiality designations …").[1] For these reasons, the Court should reject Plaintiffs' request.

That Plaintiffs are requesting this drastic measure at this late stage of the litigation betrays Plaintiffs' overreaching as nothing more than an effort to raise the cost of litigation for the ZHP Parties as the case heads toward determinations on class certification and general causation that could have dispositive effect. Were there truly a public health and safety concern warranting the wholesale de-designation of the ZHP Parties documents, Plaintiffs have had ample time to request it, and the ZHP Parties' designations clearly have not impeded Plaintiffs from prosecuting their claims over the past three years.

As previously demonstrated in the Motion, Plaintiffs have failed to establish any present or imminent public health and safety concerns that would justify de-designating any of the ten documents at issue because any public health concerns that may have existed due to and at the time of the valsartan recall have been addressed previously and extensively by the ZHP Parties themselves as well as the FDA in investigating the impurities at issue, issuing press releases and other public

[1] Plaintiffs' approach would exempt Plaintiffs from having to exercise any specificity in their confidentiality objections, and to disregard any semblance of balance and precision required by *Avandia*.

guidances, establishing consumer call centers, and other communications to valsartan users and the general public.

As Plaintiffs themselves acknowledge, all of the ZHP Parties' valsartan has been off of the U.S. market since it was voluntarily recalled over three years ago. *See* Opp. at 12. And since July 2018, the FDA has conducted an exhaustive investigation into the cause of the nitrosamine impurities in valsartan and other pharmaceuticals, resulting in numerous public announcements and communications. *See, e.g.,* Opp. at 12 (citing FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, https://tinyurl.com/1k9w9jid; FDA, *Information about Nitrosamine Impurities in Medications*, https://tinyurl.com/1tu3nih0.). While the FDA's investigation was by no means limited to the ZHP Parties, the ZHP Parties provided the FDA with unfettered access to their facilities and information related to its manufacture and distribution of valsartan. Their participation with the FDA in this endeavor was, in large part, for the purpose of informing the public of everything known about the presence of nitrosamine in their API and finished dose products.

To the extent there are any remaining health and safety concerns related to valsartan, Plaintiffs have purported to bring this litigation on behalf of all consumers of valsartan-containing drugs prior to the 2018 recall in the name of public health

and safety. *See* Third Amend. Consol. Econ. Loss Class Action Compl. at ¶ 4 (ECF No. 1708). Maintaining the confidentiality of certain of the ZHP Parties' documents would not impede Plaintiffs' ability to use those documents to prosecute their claims on behalf of the public, including the class members whom they seek to represent, subject, of course, to the rules of evidence. There is simply no basis for concluding that the widespread de-designation of the ZHP Parties' confidential documents—many of which are unrelated to valsartan—could inform the public of any current health and safety concern beyond the considerable information already available to them.

Regarding the ten documents at issue in Plaintiffs' motion, five are client communications subject to confidential disclosure agreements (two of which are duplicates); one email with a potential business partner regarding a draft process development contract; and four internal documents relating to the testing of irbesartan samples. None of these documents inform any public health or safety concern (*see* Mot. at 16-25, ECF No. 1629-3), nor do any of them suggest that disregarding the Court's carefully balanced framework for reviewing a party's confidentiality designations is warranted.

For the foregoing reasons, and those set forth in the ZHP Parties Motion, the Motion should be granted, and Plaintiffs' request for an order requiring the ZHP

Parties to re-review and de-designate their entire document production should be denied.

We thank the Court for its courtesies and consideration of this letter reply brief.

Respectfully submitted,

/s/*Seth A. Goldberg*

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